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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF IDAHO

LATISHA KENNINGTON, Plaintiff, v. COOK INCORPORATED; COOK MEDICAL LLC f/k/a COOK MEDICAL INCORPORATED; and COOK GROUP INCORPORATED, Defendants.	CIVIL ACTION NO.: 4:23-CV-96 **PLAINTIFF'S COMPLAINT** **JURY DEMANDED**

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff LATISHA KENNINGTON (hereinafter "Plaintiff"), by and through her attorney, hereby files this Plaintiff's Complaint and Demand for Jury Trial against Defendants COOK INCORPORATED; COOK MEDICAL LLC f/k/a COOK MEDICAL INCORPORATED; and COOK GROUP INCORPORATED, and alleges the following:

I. INTRODUCTION

1. This is an action for damages relating to Defendants' development, testing, assembling, manufacture, packaging, labeling, preparing, distribution, marketing, supplying,

and/or selling defective product sold under the name "inferior vena cava filter" (hereinafter "IVC filter" or "Cook IVC filter").

2. Cook IVC filters are associated with, and cause, an increased risk for serious injury and death as a result of adverse events including: tilting, perforation, fracture, breakage and migration.

3. At all times relevant to this action, Defendants intentionally, recklessly, and/or negligently failed to act as to the known failures and injuries associated with their devices and/or failed to warn about and concealed, suppressed, omitted, and/or misrepresented the risks, dangers, defects and disadvantages of their IVC filters.

4. At all times relevant to this action, Defendants intentionally, recklessly, and/or negligently advertised, labeled, promoted, marketed, sold and/or distributed their IVC filters as a safe medical device when in fact Defendants had reason to know, and/or did know, that their IVC filters were not safe for its intended purposes, and that their IVC filters caused serious injury and death.

5. At all times relevant to this action, Defendants are and were strictly liable for injuries caused by their IVC filters because the devices are unreasonably dangerous and not accompanied by adequate warnings about its danger.

II. PARTIES

6. Plaintiff LATISHA KENNINGTON at all times relevant to this action was a citizen and resident of 3102 Dewar Dr., Apt. 25, Rock Springs, Wyoming 82901.

7. Plaintiff LATISHA KENNINGTON was implanted on or about November 21,2011 with the Cook IVC filter at Eastern Idaho Regional Medical Center, 3100 Channing Way, Idaho Falls, Bonneville County, Idaho 83404.

8. Defendant Cook Incorporated is an Indiana Corporation with its principal place of business located at 750 Daniels Way, P.O. Box 489, Bloomington, Indiana. Defendant Cook Incorporated is authorized and/or doing business in the State of IDAHO including Bonneville County. At all times relevant to this action, Cook Incorporated designed, set specifications, manufactured, prepared, compounded, assembled, processed, promoted, marketed, distributed and/or sold its IVC filters to be implanted in patients throughout the United States, including IDAHO. At all times relevant hereto, Defendant Cook Incorporated was engaged in business in IDAHO, has conducted substantial business activities and derived substantial revenue from within the State of IDAHO. Defendant has also carried on solicitations or service activities in IDAHO. The registered agent for Cook Incorporated is Corporation Service Company, 135 North PENNSYLVANIA STREET, Suite 1610, Indianapolis, IN 46204. Cook Incorporated may be served with process by delivering a Summons with a copy of their Complaint attached thereto, to its registered agent.

9. On information and belief, Cook Incorporated is a privately-owned corporation with wholly owned subsidiaries that it controlled, including Cook Medical, LLC f/k/a Cook Medical Incorporated, and Cook Group Incorporated.

10. Defendant Cook Medical LLC is a privately-owned Indiana limited liability company with its principal place of business located at 1025 West Acuff Road, Bloomington, Indiana. Cook Medical LLC was formerly known as Cook Medical Incorporated. Cook Medical LLC is doing business in the state of IDAHO, including Bonneville County. Cook Medical LLC is an Indiana limited liability company whose sole member is Cook Group Incorporated. Cook Group Incorporated is incorporated under the laws of the state of Indiana and has its prinicpal place of business in Indiana. At all times relevant to this action, Cook Medical LLC designed, set

specifications, manufactured, prepared, compounded, assembled, processed, promoted, marketed, distributed and/or sold its IVC filters to be implanted in patients throughout the United States, including IDAHO. At all times relevant hereto, Defendant Cook Medical LLC was engaged in business in IDAHO has conducted substantial business activities and derived substantial revenue from within the State of IDAHO. The Defendant has also carried on solicitations or service activities in IDAHO. The registered agent for Cook Medical LLC is Corporation Service Company, 135 North PENNSYLVANIA STREET, Suite 1610, Indianapolis, Indiana. Cook Medical LLC may be served with process by delivering a Summons with a copy of their Complaint attached thereto, to its registered agent.

11. Defendant Cook Group Incorporated is an Indiana Corporation with its principal place of business located at 750 Daniels Way, P.O. Box 489, Bloomington, Indiana. Defendant Cook Group Incorporated is doing business in the State of IDAHO, including Bonneville County. At all times relevant to this action, Cook Group Incorporated designed, set specifications, manufactured, prepared, compounded, assembled, processed, promoted, marketed, distributed and sold its IVC filters to be implanted in patients throughout the United States, including IDAHO. At all times relevant hereto, Defendant Cook Group Incorporated was engaged in business, has conducted substantial business activities and derived substantial revenue from within the State of IDAHO. Defendant has also carried on solicitations or service activities in IDAHO. The registered agent for Cook Group Incorporated is Corporation Service Company, 135 North PENNSYLVANIA STREET, Suite 1610, Indianapolis, Indiana. Cook Medical Incorporated may be served with process by delivering a Summons with a copy of their Complaint attached thereto, to its registered agent.

12. Defendants Cook Incorporated, Cook Medical LLC f/k/a Cook Medical Incorporated, and Cook Group Incorporated are hereinafter collectively referred to as "Cook Defendants" or "Cook."

13. At all relevant times, the Cook Defendants were in the business of designing, setting specifications for, manufacturing, preparing, compounding, assembling, processing, marketing, packaging, and selling their IVC filters to distributors and sellers, including hospitals, for implantation by physicians at hospitals in patients throughout the United States, including in IDAHO.

14. At all relevant times, each of the Cook Defendants regularly marketed, distributed and sold their IVC filters throughout IDAHO and sold their IVC filters in IDAHO for resale and implantation into human patients, including Plaintiff.

15. At all relevant times, each of the Cook Defendants and their directors and officers acted within the scope of their authority. At all relevant times each Cook Defendant was responsible for each other's actions and inactions; and each Cook Defendant acted on behalf of each other Cook Defendant.

16. At all relevant times, the Cook Defendants possessed a unity of interest between themselves and Cook. Cook exercised control over its subsidiaries and affiliates. As such, each Cook Defendant is responsible jointly and severally to Plaintiff for her injuries, losses and damages.

III. JURISDICTION AND VENUE

17. The Court has subject matter jurisdiction over their matter because there is complete diversity of citizenship between the parties given the parties are citizens of different states and the amount in controversy exceeds $75,000, exclusive of interest and costs. *See* 28

U.S.C. § 1332. Specifically, as alleged in more detail in the PARTIES section, Plaintiff is currently a citizen of the State of Wyoming at this time, but was implanted with the Cook IVC filter in IDAHO. Cook Defendants are citizens of the State of Indiana. Cook Defendants are citizens of the State of Indiana given their principal place of business and state of incorporation, if applicable, is in Indiana. The sole member of Cook Medical LLC is Cook Group Incorporated. Cook Group Incorporated has its principal place of business in Indiana and is incorporated under the laws of the state of Indiana. Additionally, the damages Plaintiff sustained as a result of the Cook Defendants' wrongdoing substantially exceeds $75,000.

18. The Court has personal jurisdiction over the Cook Defendants because they have sufficient minimum contacts such that asserting jurisdiction over the defendants does not offend traditional notions of fair play and substantial justice. *International Shoe v. Washington*, 326 U.S. 310, 325 (1945). The Cook Defendants have conducted and continue to conduct substantial and systematic business activities related to their IVC filters in their jurisdiction. Such activities include, but are not limited to: (a) sales of IVC filters, including the Cook filter at issue in their case, in their jurisdiction; (b) hiring, training, and deploying employees, including managers and sales representatives, in their jurisdiction; (c) advertising and marketing of their IVC filters, including the Cook filter at issue in their case, in their jurisdiction; (d) maintenance of company files and equipment relating to the Cook filter in their case, in their jurisdiction; (e) payment of employee salaries in their jurisdiction; and (f) maintenance of a website directed to all states, including IDAHO. The Cook Defendants also committed tortious acts within the State of IDAHO and caused injury to persons or property within the State of IDAHO arising out of acts or omissions by the Cook Defendant outside their state at or about the time of the Plaintiff's injury, while the Cook Defendants were engaged in solicitation or service activities within the

State of IDAHO ; and/or, while products, materials, or things processed, serviced, or manufactured by the Cook Defendants were used or consumed within IDAHO in the ordinary course of commerce, trade, or use.

19. Venue is proper in their district because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred in their district, including the implantation of the Cook IVC Filter. *See* 28 U.S.C. § 1391(b)(2). The Cook Defendants' Cook filter was marketed, sold, and implanted in IDAHO.

IV. FACTUAL BACKGROUND

COOK INFERIOR VENA CAVA FILTERS GENERALLY

20. Defendants design, research, develop, manufacturer, test, market, advertise, promote, distribute, and sell products that are sold to and marketed to prevent, among other things, recurrent pulmonary embolism via placement in the vena cava. Defendants' product**s** include the Cook Celect® Vena Cava Filter and the Gunther Tulip® Filter (collectively referred to herein as "Cook IVC filters"), which are introduced via a coaxial introducer sheath system.

21. An IVC filter, like the Cook IVC filters, is a device designed to filter blood clots (called "thrombi") that travel from the lower portions of the body to the heart and lungs. IVC filters may be designed to be implanted, either temporarily or permanently, within the vena cava.

22. The inferior vena cava is a vein that returns blood to the heart from the lower portion of the body. In certain people, and for various reasons, thrombi travel from vessels in the legs and pelvis, through the vena cava into the lungs. Often these thrombi develop in the deep leg veins. The thrombi are called "deep vein thrombosis" or DVT. Once the thrombi reach the lungs they are considered "pulmonary emboli" or PE. Certain people are at an increased risk for the development of a DVT or PE such as individuals who undergo knee or hip joint replacement,

obese individuals, individuals who undergo bariatric surgery, individuals with vascular disease, among others. An IVC filter, like the Cook IVC filters, is designed to prevent thromboembolic events such as a DVT/PE.

23. When the Cook Defendants sought to enter the United States Market for IVC filters, they sought Food and Drug Administration ("FDA") approval to market the Cook IVC filters and/or its components under Section 510(k) of the Medical Device Amendment rather than the more rigorous "premarket approval" process.

24. Section 510(k) allows marketing of medical devices if the device is substantially equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of the said device. The FDA explained the difference between the 510(k) process and the more rigorous "premarket approval" process in an amicus brief filed with the Third Circuit in *Horn v. Thoratec Corp*., 376 F.3d 163, 167 (3d Cir. 2004):

> A manufacturer can obtain an FDA finding of "substantial equivalence" by submitting a premarket notification to the agency in accordance with section 510(k)…A device found to be 'substantially equivalent' to a predicate device is said to be "cleared" by FDA (as opposed to "approved" by the agency under a [premarket approval]). A pre-market notification submitted under 510(k) is thus entirely different from a [pre-market approval] which must include data sufficient to demonstrate that the device is safe and effective. (Emphasis in original).

25. In *Medtronic, Inc. v. Lohr*, 518 U.S. 470,478-79 (1996), the Supreme Court similarly described the 510(k) process, observing:

> If the FDA concludes on the basis of the [manufacturer's] §510(k) notification that the device is 'substantially equivalent' to a pre-existing device, it can be marketed without further regulatory analysis…The §510(k) notification process is by no means comparable to the [premarket approval] process; in contract to the 1,200 hours necessary to complete a PMA review, the §510(k) review is completed in average of 20 hours…Section §510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets process quickly.

26. Cook's initial Section 510(k) application was for their Gunther Tulip Vena Cava Filter. Cook positioned the Gunther Tulip Vena Cava Filter as a primarily permanent filter that happened to include a hook at its apex that facilitated a retrieval option. The Section 510(k) application for the Gunther Tulip Vena Cava Filter was submitted on October 28, 1998. On January 26, 1999, the FDA determined that the Gunther Tulip permanent and retrievable filter was "not substantially equivalent" to existing permanent filters. In particular, the FDA noted that the retrievability aspect of the device required additional clinical data.

27. Cook thereafter submitted another Section 510(k) application for the Gunther Tulip Vena Cava Filter as a filter intended for permanent placement only. However, the Cook Defendants did not alter the device in any way from the device indicated in their original 1998 submission as the retrieval hook remained a visible and usual part of the device even though no retrieval set would be sold. The FDA cleared the Gunter Tulip Vena Cava Filter for marketing as a permanent filter in 2000 – finding the device to be substantially equivalent to the Boston Scientific Greenfield Vena Cava Filter and B. Braun Medical's Vena Tech filter.

28. In September of 2000, Cook received FDA approval of a "pilot" study to access retrievability of the Gunther Tulip Vena Cava filter. The Gunther Tulip pilot study involved 41 patients who were to have filters implanted and removed within a 14-day retrieval window. Twenty-six retrievals were ultimately achieved among 41 study patients for a total of 63%. The study reported one case where the filter immediately migrated after implantation and nine other cases where the filter tilted during its implantation.

29. Based on the pilot study results and likely spurred on by the submission of a 510(k) application of a retrievable filter by the Cook Defendants' competitor, Bard Peripheral Vascular, the Cook Defendants submitted a new Section 510(k) application for a retrievable

Gunther Tulip Vena Cava filter in 2003. The Cook Defendants failed to undertake any additional studies to access the retrievability of and potential complications associated with their Gunther Tulip Vena Cava filters besides the forty-one-pilot person study where retrievals for only twenty-six individuals were successfully undertaken.

30. In October of 2003, the Gunter Tulip Vena Cava filter was approved as a retrievable device.

31. In June of 2006, the Cook Defendants submitted a Section 510(k) application for its Cook Celect Vena Cava Filter. The Cook Defendants used the Gunther Tulip Vena Cava Filter as the device to which the Celect Vena Cava Filter was substantially equivalent. Aside from the 2000 pilot study used to access retrievability of the Gunther Tulip Vena Cava filter, no additional clinical studies were conducted on the Celect Vena Cava Filter prior to its Section 510(k) submission to the FDA. Stated another way, no clinical studies accessing the retrievability of a Cook Celect – not a Cook Gunther Tulip filter – was performed in anticipation of the Cook Defendant's Section 510(k) application. The FDA cleared the Cook Celect Vena Cava Filter for marketing in April 2007.

32. Both Cook IVC filters are now marketed as optionally retrievable filters.

33. The Cook Celect® Vena Cava Filter has four (4) anchoring struts for fixation and eight (8) independent secondary struts to improve self-centering and clot trapping.

34. The Gunther Tulip® Vena Cava Filter has a top hook and (4) anchoring struts for fixation and on each strut, it has a "flower" formation that is shorter than the strut where a wire piece branches out on each side of the strut forming an overall "flower" type formation on each strut.

35. A retrospective review of all Cook Gunther Tulip filters and Cook Celect filters retrieved between July 2006 and February 2008 was performed. One hundred and thirty (130) filter retrievals were attempted but in 33 cases, the standard retrieval technique failed. The authors concluded that "unsuccessful retrieval was due to significant endothelialization and caval penetration" and that "hook endothelialization is the main factor resulting in failed retrieval and continues to be a limitation with these filters." O. Doody, et al.; "Assessment of Snared-Loop Technique When Standard Retrieval of Inferior Vena Cava Filters Fail," Cardiovasc Intervent Radiol (Sept 4, 2008 Technical Note).

36. A retrospective review of 115 patients who underwent Cook Celect IVC filter insertion between December 2005 and October 2007 was performed. While filter insertion was successful in all patients, the authors also concluded that "[f]ailed retrieval secondary to hook endothelialization continues to be an issue with their filter." O. Doody, et al; Journal of Medical Imaging and Radiation Oncology "Initial Experience in 115 patients with the retrievable Cook Celect vena cava filter" 53 (2009) 64-68 (original article).

37. In a review of clinical data related to 73 patients who had Celect IVC filters implanted between August 2007 and June 2008, the authors found that the Celect IVC filter was related to a high incidence of caval filter leg penetration. Immediately after fluoroscopy-guided filter deployment in 61 patients, four filters (6.5%) showed significant tilt. Follow-up abdominal CT in 18 patients demonstrated filter related problems in 7 (39%), which included penetration of filter legs in 4 and fracture/migration of filter components in 1.

38. In a study of Gunther Tulip and Celect IVC filters implanted between July 2007 and May of 2009 reported by Cardiovascular Interventional Radiology electronically on March 30, 2011 and published by journal in April 2012, one hundred percent of the Cook Celect filters

and Gunther Tulip filters imaged after 71 days of implant caused some degree of filter perforation of the venal caval wall. Durack JC, et al, Cardiovasc Intervent Radiol., "Perforation of the IVC: rule rather than the exception after longer indwelling times for the Gunther Tulip and Celect Retrievable Filters," 2012 Apr.; 35(2):299-308. Epub 2011, Mar 30. The authors concluded: "Although infrequently reported in the clinical literature, clinical sequelae from IVC filter components breaching the vena cava can be significant." Defendants knew or should have known that their IVC filters were more likely than not to perforate the vena cava wall.

39. The same study reported that tilt was seen in 20 out of 50 (40%) of the implanted Gunther Tulip and Celect IVC filters and all tilted filters also demonstrated vena caval perforation. Defendants knew or should have known that their IVC filters were more likely than not to tilt and to perforate.

40. On May 6, 2014, the FDA released an updated Safety Communication on IVC Filter Retrieval. The update stated that retrievable IVC Filters (including the Cook Celect and Gunther Tulip filters) should be removed as soon as the risk of pulmonary embolism subsided. The FDA developed a quantitative decision analysis using publicly available data from the medical literature to assess whether there is a time period during which the risk of having an IVC filter is expected to outweigh the benefits. In October 2013, Jose Pablo Morales, MD, et al published the decision analysis in the Journal of Vascular Surgery: Venous and Lymphatic Disorders (2013;1:376–384). The mathematical model suggested that if the patient's transient risk for pulmonary embolism has passed, the risk/benefit profile begins to favor removal of the IVC filter between 29 and 54 days after implantation.

41. On July 19, 2019, another study published in the New England Journal of Medicine, of the effectiveness of all retrievable filters was conducted concerning 240 severely

injured patients, the study concluded that placement of vena cava filters after major trauma did not result in a lower incident rate of pulmonary embolism than those who did not have a filter implanted.

42. The study used both Cook and Bard IVC filters, 117 patients received Bard Denali filters, and 5 received Cook Celect filters. The study was published with its results, including the following:

- An entrapped thrombus was found within the filter in almost 5% of the patients.
- Placement of the filter (within 72 hours after injury) did not result in a lower rate of pulmonary embolisms or death at 90 days which again is the very condition Cook told the FDA, physicians, and the public its filters were designed to prevent including the Gunther Tulip and the Celect Filter.

43. While not inclusive of all medical studies published during the relevant time period, the above references show that the Cook Defendants failed to disclose to physicians, patients and/or Plaintiff that their Cook IVC filters were subject to breakage, tilt, inability of removal, perforation, and migration even though they knew or should have known the same was true**.**

44. Although the Cook Defendants knew or should have known that Cook IVC filters were subject to breakage, tilt, inability, perforation, and migration, the Cook Defendants failed to recall, retrofit, and/or warn of the danger of their Cook IVC filters when a reasonable manufacturer, distributor, or seller under the same or similar circumstances would have recalled, retrofitted, and/or warned of the dangers of these products.

45. At all times relevant hereto, the Cook Defendants continued to promote Cook IVC filters as safe and effective even when inadequate clinical trials had been performed to support long or short to safety and/or efficacy.

46. At all times relevant hereto, the Cook IVC filters were widely advertised and promoted by the Defendants as safe and effective treatment for prevention of recurrent pulmonary embolism via placement in the vena cava.

47. At all times, Cook advertised through its Instructions for Use ("IFU"), Patient Brochure, and other representations by Cooks sales representatives and other marketing material that the filter could remain permanently, and it was at a doctor's discretion when he or she could remove the filter, downplaying the risks of the filter remaining indwelled longer than the FDA recommended 29-54 days.

48. At all times relevant hereto, the Cook Defendants knew their Cook IVC filters were defective and knew that defect was attributable to the design's failure to withstand the normal anatomical and physiological loading cycles exerted *in vivo.*

49. At all relevant times hereto, the Cook Defendants concealed the known risks and failures of their Cook IVC filters and failed to warn of known or scientifically knowable.

50. The Defendants concealed the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Cook IVC filters, as aforesaid.

51. The Cook IVC filters are constructed of conichrome.

52. The Defendants specifically advertise the conichrome construction of the filter as a frame which "reduces the risk of fracture."

53. The failure of the Cook IVC filters is attributable, in part, to the fact that the Cook IVC filters suffer from a design defect causing it to be unable to withstand the normal anatomical and physiological loading cycles exerted *in vivo.*

54. At all times relevant hereto, the Defendants failed to provide sufficient warnings and instructions that would have put Plaintiff and the general public on notice of the dangers and adverse effects caused by implantation of the Cook IVC filters, including, but not limited to the design's failure to withstand the normal anatomical and physiological loading cycles exerted *in vivo.*

55. The Cook IVC filters were designed, manufactured, distributed, sold and/or supplied by the Defendants, and were marketed while defective due to the inadequate warnings, instructions, labeling, and/or inadequate testing in light of Defendants' knowledge of the products' failure and serious adverse events.

56. That at all times relevant hereto, the officers and/or directors of the Defendants named herein participated in, authorized and/or directed the production and promotion of the aforementioned products when they knew or should have known of the hazardous and dangerous propensities of the said products, and thereby actively participated in the tortious conduct that resulted in the injuries suffered by the Plaintiff.

PLAINTIFF'S COOK FILTER AND INJURIES

57. On or about November 11, 2011, Plaintiff LATISHA KENNINGTON was implanted with a Cook GUNTHER TULIP "Tulip" Filter in Idaho Falls, IDAHO, for prevention of Deep Vein Thrombosis and Pulmonary Embolism.

58. In December 2021, Plaintiff had a CT scan which showed that the filter is perforating over 8 mm into her left iliac vein, with multiple other struts perforating the IVC between 9 and 4 mm.

59. Plaintiff is at risk for future Cook Filter fractures, migrations, perforations, and tilting. Plaintiff faces numerous health risks, including the risk of death.

60. For the rest of her life, Plaintiff will require ongoing medical care and monitoring.

61. Plaintiff has also suffered significant, disfiguring injuries, including significant pain and distress restricting her ability to engage in activities of daily living.

62. Furthermore, Plaintiff has incurred substantial medical expenses as a result of Cook's defective device, and, on information and belief, she will continue to incur substantial medical expenses in the future.

V. COUNT I: STRICT PRODUCTS LIABILITY – FAILURE TO WARN

63. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein. Plaintiff further restates and incorporates in full the FACTUAL BACKGROUND section in full and further alleges as follows:

64. At all times relevant to this action, the Cook Defendants designed, tested, manufactured, packaged, labeled, marketed, distributed, promoted, and sold their Cook IVC filters, including the IVC filter implanted into Plaintiff, placing the devices into the stream of commerce.

65. Cook IVC filters were defective and unreasonably dangerous when they left the possession and/or control of the Defendants in that they contained warnings/instructions/labels insufficient and/or inadequate to alert and/or communicate to consumers, including Plaintiff, of the reasonably foreseeable dangerous, nonobvious risks and/or dangers associated with the

subject product's condition and/or normal use, including but not limited to the risk of tilting, perforation, fracture and migration which are associated with and did cause serious injury and/or death.

66. Cook IVC filters were defective and unreasonably dangerous before they left the possession and/or control of the Defendants in that they contained warnings/instructions/labels insufficient and/or inadequate to alert and/or communicate to consumers, including Plaintiff, of the reasonably foreseeable dangerous, nonobvious risks associated with the subject product's condition and/or normal use, including but not limited to the risk of tilting, perforation, fracture and migration which are associated with and did cause serious injury and/or death.

67. At all times relevant hereto, the Cook IVC filters were widely advertised and promoted by the Defendants as safe and effective treatment for prevention of recurrent pulmonary embolism via placement in the vena cava. At all times relevant hereto, Defendants knew their Cook IVC filters were of inferior quality, condition, and/or character and had dangerous risks, including but not limited to the risk of tilting, perforation, fracture and migration which are associated with and did cause serious injury and/or death.

68. The Cook Defendants either actually knew of or could have known in light of the scientific and medical knowledge generally accepted in the scientific community that the Cook IVC had the potential risk of tilting, perforation, fracture and migration which are associated with and did cause serious injury and/or death, yet marketed the Cook IVC filters without adequately warning of the danger or providing instructions for safe use at the time of the Cook IVC filter's sale to Plaintiff.

69. Cook either actually knew of and could reasonably foresee that Plaintiff was a direct or reasonably foreseeable user, or person in Plaintiff's position might reasonably be expected to come in contact with, use, and/or reasonably be affected by the Cook IVC filter.

70. Cook either knew of and could reasonably foresee the dangerous risks associated with the subject product's condition, including but not limited to the risk of tilting, perforation, fracture and migration which are associated with and did cause serious injury and/or death, yet marketed the Cook IVC filters without adequately warning of the danger or providing instructions for safe use.

71. Cook either actually knew of and could reasonably foresee the dangerous risks associated with the Cook IVC filter, including but not limited to the risk of tilting, perforation, fracture, and migration which are associated with and did cause serious injury and/or death, presented a substantial danger to the ordinary consumer, including Plaintiff, when the Cook IVC filter was used in the intended way.

72. Cook either actually knew of, should have known of, and could reasonably foresee and anticipate the dangerous risks associated with the Cook IVC filter, including but not limited to the risk of tilting, perforation, fracture, and migration which are associated with and did cause serious injury and/or death, presented a substantial danger to the ordinary consumer, including Plaintiff, when the Cook IVC filter was used in a reasonably foreseeable way and/or manner.

73. Cook either actually knew of, should have known of, and could reasonably foresee and/or anticipate the dangerous risks associated with the Cook IVC filter, including but not limited to the risk of tilting, perforation, fracture, and migration which are associated with and did cause serious injury and/or death, presented a substantial danger to the ordinary

consumer, including Plaintiff, when the Cook IVC filter was misused in a reasonably foreseeable way and/or manner.

74. The omission of adequate and sufficient warnings, labels, and instructions with respect to the Cook IVC filter, rendered the filter unreasonably dangerous and defective to Plaintiff.

75. The Cook Defendants failed to use and exercise the reasonable amount of care in designing, manufacturing, inspection, marketing, promoting, warning, and reporting that a reasonably careful manufacturer of a device similar to the Cook IVC filter would have used to avoid exposing ordinary consumers, such as Plaintiff, to the foreseeable risks of harm, including but not limited to, the risk of tilting, perforation, fracture, and migration which are associated with and may cause serious injury and death.

76. The dangerous risks associated with the Cook IVC filter, including but not limited to the risk of tilting, perforation, fracture, and migration which are associated with and caused serious injury and may lead to death, where not generally known or recognized.

77. Information provided by Cook to the medical community and to consumers concerning the safety and efficacy of its Cook IVC filters did not accurately reflect the serious and potentially fatal adverse events Plaintiff could suffer.

78. At all times relevant hereto, the Cook IVC filters were dangerous and presented a substantial danger to patients who were implanted with the Cook IVC filter, and these risks and dangers were known or knowable at the times of distribution and implantation in Plaintiff. Ordinary consumers, including Plaintiff, would not have recognized the potential risks and dangers the Cook IVC filters posed to patients, because their use was specifically promoted to improve health of such patients.

79. Had adequate warnings, labels, and instructions been provided by the Cook Defendants, Plaintiff would not have been implanted with the Cook IVC filter and any risk of the harmful injuries described herein could have been reduced or avoided by the provision of reasonable instructions or warnings.

80. Had adequate warnings, labels, and instructions been provided, Plaintiff would not have been implanted with the Cook IVC filter and would not have been at risk of the harmful injuries described herein. The Cook Defendants failed to provide warnings of such risks and dangers to Plaintiff and their medical providers as described herein. Neither Plaintiff, nor Plaintiff's physicians knew, nor could they have expected and learned through the exercise of reasonable care, the risks of serious injury and/or death associated with and/or caused by Cook's IVC filters.

81. Had adequate warnings, labels, and instructions been provided, Plaintiff and/or Plaintiff's physician would have followed the Cook IVC filter's warnings or instructions and Plaintiff would not have been at risk of the harmful injuries described herein. The Cook Defendants failed to provide warnings of such risks and dangers to Plaintiff and their medical providers as described herein. Neither Plaintiff, nor Plaintiff's physicians knew, nor could they have expected and learned through the exercise of reasonable care, the risks of serious injury and/or death associated with and/or caused by Cook's IVC filters.

82. A reasonably prudent manufacturer in the same or similar circumstances would have provided with respect to the risks of serious injury and/or death associated with and/or caused by Cook's IVC filters and would have communicated adequate information on the risks of serious injury and/or death associated with and/or caused by Cook's IVC filters and safe use

of the Cook IVC filter, taking into account the characteristics of, and the ordinary knowledge common to, the persons by whom the product is intended to be used.

83. Cook Defendants knew or had knowledge that the warnings that were given failed to properly and adequately warn of the increased risks of serious injury and/or death associated with and/or caused by Cook IVC filters.

84. Plaintiff, individually and through their implanting physician, reasonably and justifiably relied upon the skill, superior knowledge, and judgment of the Cook Defendants.

85. Cook Defendants were under a continuing duty to warn Plaintiff and their physicians of the foreseeable nonobvious dangers associated with the filter, even after the Cook IVC filter had left the possession, custody, and/or control of Defendant Cook.

86. Cook Defendants were under a continuing duty to warn Plaintiff and their physicians of the foreseeable nonobvious dangers associated with the normal use of the Cook IVC filter, even after the Cook IVC filter had left the possession, custody, and/or control of Defendant Cook.

87. Cook Defendants were under a continuing duty to warn Plaintiff and their physicians of the foreseeable nonobvious dangers associated with the normal misuse in a reasonably foreseeable way and/or manner of the Cook IVC filter, even after the Cook IVC filter had left the possession, custody, and/or control of Defendant Cook.

88. The Cook Defendants were under a continuing duty to design and manufacture IVC filters that were free from unreasonable, foreseeable, nonobvious dangers and/or injuries associated with the normal use and misuse in a reasonably foreseeable way and/or manner of the Cook IVC filter, even after the Cook IVC filter had left the possession, custody, and/or control of Defendant Cook.

89. The Cook Defendants were under a continuing duty to design and/or manufacture IVC filters that eliminate any unreasonable, foreseeable, nonobvious dangers and/or injuries associated with the normal use and misuse in a reasonably foreseeable way and/or manner of the Cook IVC filter, even after the Cook IVC filter had left the possession, custody, and/or control of Defendant Cook

90. The warnings, labeling, and instructions provided were inadequate insofar as, in light of the ordinary knowledge common to members of the manufacturing community, medical community, and/or general public who use the product, it was not designed to reasonably catch the user's attention; nor was the filter understandable to foreseeable users; nor did the filter fairly indicated the danger from the filter's foreseeable use and/or misuse; and was insufficiently conspicuous to match the magnitude of the danger; because the warnings, labeling, and instructions failed to properly warn of the dangerous risks of harm, including but not limited to, the risk of tilting, perforation, fracture, and migration which are associated with and did cause serious injury and/or death.

91. Safer alternatives were available that were effective and without risks posed by Cook's IVC filters.

92. As a direct and proximate result of the Cook IVC filter's defects and/or condition, as described herein, Plaintiff suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost their ability to live a normal life and will continue to be so diminished into the future. Furthermore, Plaintiff has medical bills, both past and future, related to care because of the Cook IVC filters' defects.

93. The Cook Defendants' failure to provide sufficient instructions, warnings, and/or labels substantially contributed to Plaintiff's permanent and continuous injuries, pain and suffering, disability and impairment, emotional trauma, harm, and injuries that will continue into the future.

94. By reason of the foregoing, Cook Defendants are liable to Plaintiff for damages as a result of their failure to warn and/or adequately warn the Plaintiff and their healthcare professionals about the increased risk of serious injury and death caused by their defective Cook IVC filters.

95. **WHEREFORE**, Plaintiff demands judgment against the Cook Defendants and seeks damages, including compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and other such other and further relief as the Court deems just and proper.

VI. COUNT II: STRICT PRODUCTS LIABILITY – DESIGN DEFECT

96. Plaintiff repeats and realleges all previous paragraphs and restates and incorporates the FACTUAL BACKGROUND section by reference.

97. At all times relevant to their cause of action, the Cook Defendants were in the business of designing, developing, manufacturing, marketing, and selling sophisticated medical devices, including their Cook IVC filters.

98. At all times relevant hereto, the Cook Defendants were under a duty to act reasonably and use prudent care to design, develop, manufacture, market, inspect, plan, and sell a product that did not present a risk of unforeseeable and unreasonable risk of harm or injury to the Plaintiff and to those people receiving their Filters.

99. At all times relevant to Plaintiff's action, Cook Defendants designed, tested, inspected, manufactured, assembled, developed, labeled, licensed, marketed, advertised, promoted, packaged, distributed, and sold their Cook IVC filters, placing the devices into the stream of commerce.

100. At all times relevant to Plaintiff's action, the Cook IVC filter posed a substantial danger of harm to the foreseeable consumer and/or user, including Plaintiff, insofar that the Cook IVC filter's condition and/or quality posed dangerous risks, including but not limited to the risk of tilting, perforation, fracture and migration which are associated with and did cause serious injury and/or death.

101. At all times relevant to Plaintiff's action, Cook's IVC filters were designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed by Cook Defendants in a condition that was defective and unreasonably dangerous to consumers, including Plaintiff.

102. Cook knew or should have known that the IVC filter was dangerous or was likely to be unreasonably dangerous when used in its intended, reasonably foreseeable, and/or probable manner and/or use.

103. The Cook Defendants failed to use the amount of care in designing, manufacturing, inspection, marketing, promoting, and reporting that a reasonably careful manufacturer of a device similar to the Cook IVC filter would have used to avoid exposing ordinary consumers, such as Plaintiff, to the foreseeable risks of harm, including but not limited to, the risk of tilting, perforation, fracture, and migration which are associated with and did cause serious injury and/or death.

104. Cook either actually knew of or could reasonably foresee the dangerous risks associated with the subject product, including but not limited to the risk of tilting, perforation, fracture and migration which are associated with and did cause serious injury and/or death, yet marketed the Cook IVC filters without adequately warning of the danger or providing instructions for safe use.

105. The ordinary consumer, including Plaintiff, would not know of the dangerous risks associated with the subject product, including but not limited to the risk of tilting, perforation, fracture and migration which are associated with and did cause serious injury and/or death.

106. The ordinary consumer, including Plaintiff, would not know of the dangerous risks associated with the subject product and would not be able to avoid the dangers and/or risks, including but not limited to the risk of tilting, perforation, fracture and migration which are associated with and did cause serious injury and/or death.

107. The ordinary consumer, including Plaintiff, would find the dangerous risks associated with the subject product, including but not limited to the risk of tilting, perforation, fracture and migration which are associated with and did cause serious injury and/or death unacceptable.

108. Cook IVC filters were and are unreasonably dangerous in that, as designed, failed to perform safely when used by ordinary consumers, including Plaintiff, including when the filters were used as intended and in a reasonably foreseeable manner.

109. The Cook IVC filters' foreseeable risks of harm posed could have been reduced or avoided by the provision of reasonable instructions or warning and their omission of said warnings rendered the Cook IVC filter not reasonably safe when used by foreseeable ordinary

consumers, including Plaintiff, including when the filters were used as intended and in a reasonably foreseeable manner, in that the Cook IVC filter posed a risk of serious vascular and other serious injury which could have been reduced or avoided, inter alia, by the adoption of a feasible and/or reasonable instructions or warnings.

110. A reasonable manufacturer of a device similar to the Cook IVC filter under the same or similar circumstances would have warned and/or instructed of the safe use of the product and given warnings and/or instructions regarding the reasonably foreseeable risks of the device similar to the Cook IVC filter.

111. Cook either actually knew of or could reasonably foresee that Plaintiff was a direct or reasonably foreseeable user, or person in Plaintiff's position might reasonably be expected to come in contact with the Cook IVC filter.

112. At the time of manufacture and sale of the Cook IVC filters, the Cook Defendants knew or reasonably should have known the Cook IVC filters:

a. were designed and manufactured in such a manner so as to present an unreasonable risk of fracture of portions of the device, as aforesaid;

b. were designed and manufactured so as to present an unreasonable risk of migration of the device and/or portions of the device, as aforesaid;

c. were designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body; and/or

d. were designed and manufactured so as to present an unreasonable risk of perforation and damage to the vena caval wall.

113. Despite the aforementioned duties on the part of the Cook Defendants, they committed one or more breaches of their duty of reasonable care and were negligent in:

a. unreasonably and carelessly failing to properly warn of the dangers and risks of harm associated with the Cook Filters, specifically its incidents fracture, migration, perforation and other failure;

b. unreasonably and carelessly manufacturing a product that was insufficient in strength or structural integrity to withstand the foreseeable use of normal placement within the human body;

c. unreasonably and carelessly designed a product that was insufficient in strength or structural integrity to withstand the foreseeable use of normal placement within the human body; and

d. unreasonably and carelessly designed a product that presented a risk of harm to the Plaintiff and others similarly situated in that it was prone to fail.

114. A reasonably careful manufacturer of a medical devise akin to the Cook IVC filter would not have:

a. unreasonably and carelessly failing to properly warn of the dangers and risks of harm associated with the Cook Filters, specifically its incidents fracture, migration, perforation and other failure;

b. unreasonably and carelessly manufacturing a product that was insufficient in strength or structural integrity to withstand the foreseeable use of normal placement within the human body;

c. unreasonably and carelessly designed a product that was insufficient in strength or structural integrity to withstand the foreseeable use of normal placement within the human body; and

d. unreasonably and carelessly designed a product that presented a risk of harm to the Plaintiff and others similarly situated in that it was prone to fail.

115. Physicians implanted as instructed via the Instructions for Use and in a foreseeable manner as normally intended, recommended, promoted, and marketed by the Cook Defendants. Plaintiff received and utilized Cook IVC filters in a foreseeable manner as normally intended recommend, promoted, and marketed by the Cook Defendants.

116. The Cook IVC filters were unreasonably dangerous in that the filter failed to perform as safely as an ordinary consumer, including Plaintiff, would have expected when implanted and/or in a manner reasonably foreseeable by Plaintiff's physicians in that the risks of tilting, perforation, fracture, migration, and death far outweighed any alleged benefits of the Cook IVC filter.

117. Cook IVC filters were and are unreasonably dangerous and defective in design or formulation for their intended use in that, when they left the hands of the manufacturers and/or supplier, they posed a risk of serious vascular and other serious injury which could have been reduced or avoided, inter alia, by the adoption of a feasible reasonable alternative design. There were safer alternative designs for the like products.

118. Cook IVC filters were insufficiently tested and caused harmful adverse events that outweighed any potential utility.

119. Cook IVC filters were defective and unreasonably dangerous at the time they left the possession and control of the Defendants in that they contained warnings/instructions insufficient and/or inadequate to alert consumers, including Plaintiff, of the dangerous risks associated with the subject product, including but not limited to the risk of tilting, perforation, fracture and migration which are associated with and did cause serious injury and/or death.

120. Defendants insufficient warnings/instructions of the dangerous risks associated with the subject product, including but not limited to the risk of tilting, perforation, fracture and migration which are associated with and did cause serious injury and/or death was the cause and/or substantial factor in Plaintiff's permanent and continuous injuries, pain and suffering, disability, impairment, emotional trauma, harm, injuries that will continue into the future, and loss of the ability to live a normal life.

121. Cook IVC filters were defective and unreasonably dangerous at the time they left the possession and control of the Defendants and did not undergo substantial change.

122. Cook IVC filters are defective in their design and/or formulation in that they are not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with their design and formulation.

123. Cook IVC filters were expected to reach, and did reach, users and/or consumers including Plaintiff, without substantial change in the defective and unreasonably dangerous condition in which they were manufactured and sold.

124. Cook IVC filters, as manufactured and supplied, were defective due to inadequate warnings, and/or inadequate clinical trials, testing, and study, and inadequate reporting regarding the results of the clinical trials, testing and study.

125. Cook IVC filters, as manufactured and supplied, were defective due to its no longer being substantially equivalent to its predicate device with regard to safety and effectiveness.

126. Cook IVC filters, were defective and of an unreasonably dangerous nature, unlike the safer Medi-tech (Boston Scientific) Greenfield Stainless Steel Vena Cava Filter - 12 F (k912035).

127. The Medi-tech (Boston Scientific) Greenfield Stainless Steel Vena Cava Filter - 12 F (k912035) is still available on the market and uses a safer alternative design.

128. The alternative design of the Medi-tech (Boston Scientific) Greenfield Stainless Steel Vena Cava Filter - 12 F (k912035) is both practical and feasible for Cook.

129. Cook could have designed the Cook IVC in a similar manner to the Medi-tech (Boston Scientific) Greenfield Stainless Steel Vena Cava Filter - 12 F (k912035), which would have minimized or eliminated the risks of harm to Plaintiff.

130. If Cook had used the safer alternative design it would have prevented or significantly reduced the risk of the plaintiff's personal injury, property damage, or death without substantially impairing the product's utility.

131. The safer alternative design was economically and technologically feasible at the time the product left the control of the manufacturer or seller by the application of existing or reasonably achievable scientific knowledge.

132. Cook IVC filters as manufactured and supplied by the Cook Defendants are and were defective due to inadequate post-marketing warnings or instructions because, after Cook Defendants knew or should have known of the risk of injuries from use and acquired additional knowledge and information confirming the defective and dangerous nature of their Cook IVC filters, Cook Defendants failed to provide adequate warnings to the medical community and the consumers, to whom Cook Defendants were directly marketing and advertising; and further, Cook Defendants continued to affirmatively promote their Cook IVC filters as safe and effective and as safe and effective as their predicate device.

133. A reasonable person would conclude the probability and seriousness of harm associated with the foreseeable risks of the Cook IVC filter, when used in an intended or

reasonably foreseeable manner and/or use, outweigh the benefits, burden, and/or costs of taking precautions.

134. As a direct, proximate, and legal cause of the Cook IVC filter's defects and/or condition, as described herein, Plaintiff has suffered permanent and continuous injuries, pain and suffering, disability, physical harm, and impairment. Plaintiff has suffered emotional trauma, harm, and injuries that will continue into the future. Plaintiff has lost the ability to live a normal life, and will continue to be so diminished into the future. Furthermore, Plaintiff has medical bills both past and future related to care because of the Cook Filter's defects.

135. The Cook Defendants' failure to provide sufficient instructions, warnings, and/or labels substantially contributed to Plaintiff's permanent and continuous injuries, pain and suffering, disability and impairment, emotional trauma, harm, and injuries that will continue into the future.

136. By reason of the foregoing, Cook Defendants are liable to the Plaintiff for damages as a result of their failure to warn and/or adequately warn the Plaintiff and their healthcare professionals about the increased risk of serious injury and death caused by their defective Cook IVC filters.

137. **WHEREFORE**, Plaintiff demands judgment against the Cook Defendants and seeks damages, including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other an further relief as the Court deems just and proper.

VII. COUNT III: NEGLIGENCE

138. Plaintiff repeats and realleges all previous paragraphs and restates and incorporates the FACTUAL BACKGROUND section by reference.

139. At all times relevant to their cause of action, the Cook Defendants were in the business of designing, developing, manufacturing, marketing, and selling sophisticated medical devices, including their Cook IVC filters.

140. At all times relevant hereto, the Cook Defendants were under a duty to act reasonably and use prudent care to design, develop, manufacture, market, inspect, and sell a reasonably safe product that did not present a risk of unforeseeable and unreasonable risk of harm or injury to the Plaintiff and to those people receiving their Filters.

141. As demonstrated in the FACTUAL BACKGROUND section, Cook knew or should have known that the IVC filter was dangerous or was likely to be unreasonably dangerous when used in its intended or reasonably foreseeable manner. Before Plaintiff's Cook IVC filter was implanted, data established that the failure rate of Plaintiff's Cook IVC filter was (and remains) exceedingly higher than the rates the Cook Defendants have published in the past, and currently continue to publish to the medical community, members of the public, and the FDA. Further, unbeknownst to the Plaintiff at the time of implantation, the Cook Defendants did not adequately test their Cook IVC filters for safety, efficacy, or retrievability before marketing of the Cook IVC filter.

142. The Cook Defendants failed to use and exercise the reasonable amount of care in designing, manufacturing, inspection, marketing, promoting, warning, and reporting that a reasonably careful manufacturer of a device similar to the Cook IVC filter would have used to avoid exposing ordinary consumers, such as Plaintiff, to the foreseeable risks of harm, including but not limited to, the risk of tilting, perforation, fracture, and migration which are associated with and did cause serious injury and/or death.

143. Cook Defendants were under a continuing duty to warn Plaintiff and their physicians of the foreseeable nonobvious dangers associated with the filter, even after the Cook IVC filter had left the possession, custody, and/or control of Defendant Cook.

144. Cook Defendants were under a continuing duty to warn Plaintiff and their physicians of the foreseeable nonobvious dangers associated with the normal use of the Cook IVC filter, even after the Cook IVC filter had left the possession, custody, and/or control of Defendant Cook.

145. Cook Defendants were under a continuing duty to warn Plaintiff and their physicians of the foreseeable nonobvious dangers associated with the normal misuse in a reasonably foreseeable way and/or manner of the Cook IVC filter, even after the Cook IVC filter had left the possession, custody, and/or control of Defendant Cook.

146. Defendant Cook expected the Cook IVC filters to reach consumers, including Plaintiff, who was implanted with her Cook IVC filter as a prophylactic measure ahead of an anticipated surgery.

147. The Cook IVC filter did reach consumers, including Plaintiff, who was implanted with her Cook IVC filter as a prophylactic measure ahead of an anticipated surgery.

148. At the time Cook IVC filter reached Plaintiff it had not undergone any substantial changes in condition and/or design from the time the Cook IVC filter left the possession, custody, and/or control of Defendant Cook.

149. Cook either actually knew of or could reasonably foresee the unreasonably dangerous risks associated with the subject product, including but not limited to the risk of tilting, perforation, fracture and migration which are associated with and did cause serious injury

and/or death, yet marketed the Cook IVC filters without adequately warning of the danger or providing instructions for safe use.

150. A reasonable manufacturer of a device similar to the Cook IVC filter under the same or similar circumstances would have warned and/or instructed of the safe use of the product and given warnings and/or instructions regarding the reasonably foreseeable unreasonable risks of the device similar to the Cook IVC filter.

151. Cook IVC filters were defective and unreasonably dangerous when they left the possession and/or control of the Defendants in that they contained warnings/instructions/labels insufficient and/or inadequate to alert and/or communicate to consumers, including Plaintiff, of the foreseeable dangerous nonobvious risks and/or dangers associated with the subject product's condition and/or normal use, including but not limited to the risk of tilting, perforation, fracture and migration which are associated with and did cause serious injury and/or death.

152. Cook IVC filters were defective and unreasonably dangerous before they left the possession and/or control of the Defendants in that they contained warnings/instructions/labels insufficient and/or inadequate to alert and/or communicate to consumers, including Plaintiff, of the foreseeable dangerous nonobvious risks associated with the subject product's condition and/or normal use, including but not limited to the risk of tilting, perforation, fracture and migration which are associated with and did cause serious injury and/or death.

153. Cook either actually knew of or could reasonably foresee that Plaintiff was a direct or reasonably foreseeable user, or person in Plaintiff's position might reasonably be expected to come in contact with the Cook IVC filter.

154. The Cook Defendants failed to provide warnings, labels, and /or instructions of the unreasonable risks of including but not limited to the risk of tilting, perforation, fracture and

migration which are associated with and did cause serious injury and/or death, to Plaintiff. Nor could Plaintiff and/or Plaintiff's physician have learned through the exercise of reasonable care, the unreasonable risks of serious injury and/or death associated with and/or caused by Cook's IVC filters.

155. At the time of manufacture and sale of the Cook IVC filters, the Cook Defendants knew or reasonably should have known the Cook IVC filters:

a. were designed and manufactured in such a manner so as to present an unreasonable risk of fracture of portions of the device, as aforesaid;

b. were designed and manufactured so as to present an unreasonable risk of migration of the device and/or portions of the device, as aforesaid;

c. were designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body; and/or

d. were designed and manufactured so as to present an unreasonable risk of perforation and damage to the vena caval wall.

156. Despite the aforementioned duties on the part of the Cook Defendants, they committed one or more breaches of their duty of reasonable care and were negligent in:

a. unreasonably and carelessly failing to properly warn of the dangers and risks of harm associated with the Cook Filters, specifically its incidents fracture, migration, perforation and other failure;

b. unreasonably and carelessly manufacturing a product that was insufficient in strength or structural integrity to withstand the foreseeable use of normal placement within the human body;

c. unreasonably and carelessly designed a product that was insufficient in strength or structural integrity to withstand the foreseeable use of normal placement within the human body; and

d. unreasonably and carelessly designed a product that presented a risk of harm to the Plaintiff and others similarly situated in that it was prone to fail.

157. A reasonably careful manufacturer of a medical devise akin to the Cook IVC filter would not have:

a. unreasonably and carelessly failing to properly warn of the dangers and risks of harm associated with the Cook Filters, specifically its incidents fracture, migration, perforation and other failure;

b. unreasonably and carelessly manufacturing a product that was insufficient in strength or structural integrity to withstand the foreseeable use of normal placement within the human body;

c. unreasonably and carelessly designed a product that was insufficient in strength or structural integrity to withstand the foreseeable use of normal placement within the human body; and

d. unreasonably and carelessly designed a product that presented a risk of harm to the Plaintiff and others similarly situated in that it was prone to fail.

158. Cook IVC filters were defective and unreasonably dangerous at the time they left the possession and control of the Defendants in that they contained warnings/instructions insufficient and/or inadequate to alert consumers, including Plaintiff, of the dangerous risks associated with the subject product, including but not limited to the risk of tilting, perforation, fracture and migration which are associated with and did cause serious injury and/or death.

159. Defendants insufficient warnings/instructions of the dangerous risks associated with the subject product, including but not limited to the risk of tilting, perforation, fracture and migration which are associated with and did cause serious injury and/or death was the cause and/or substantial factor in Plaintiff's permanent and continuous injuries, pain and suffering, disability, impairment, emotional trauma, harm, injuries that will continue into the future, and loss of the ability to live a normal life.

160. Cook IVC filters were defective and unreasonably dangerous at the time they left the possession and control of the Defendants and did not undergo substantial change.

161. As a direct, proximate, and legal cause of the Cook IVC filter's defects, as described herein, Plaintiff has suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost the ability to live a normal life, and will continue to be so diminished into the future. Furthermore, Plaintiff has medical bills both past and future related to care because of the Cook Filter's defects.

162. The Cook Defendants' failure to provide sufficient instructions, warnings, and/or labels substantially contributed to Plaintiff's permanent and continuous injuries, pain and suffering, disability and impairment, emotional trauma, harm, and injuries that will continue into the future.

163. Had the Cook Defendants' provided sufficient and/or proper instructions, warnings, and/or labels to Plaintiff and/or Plaintiff's physician, there is a reasonable likelihood that an adequate warning would have been provided to Plaintiff and Plaintiff would have altered their behavior and chose not to have the Cook IVC filter implanted; thus avoiding Plaintiff's

permanent and continuous injuries, pain and suffering, disability and impairment, emotional trauma, harm, and injuries that will continue into the future.

164. By reason of the foregoing, Cook Defendants are liable to the Plaintiff for damages as a result of their failure to warn and/or adequately warn the Plaintiff and their healthcare professionals about the increased risk of serious injury and death caused by their defective Cook IVC filters.

165. **WHEREFORE**, Plaintiff demands judgment against the Cook Defendants and seeks damages, including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other an further relief as the Court deems just and proper.

VIII. COUNT IV NEGLIGENCE- FAILURE TO WARN

166. Plaintiff repeats and realleges all previous paragraphs and restates and incorporates the FACTUAL BACKGROUND section by reference.

167. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the Cook Filter, including the one implanted into Plaintiff, into the stream of commerce and in the course of same, directly advertised and marketed the device to consumers or persons responsible for consumers.

168. At the time Defendants designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the device into the stream of commerce, Defendants knew or should have known the device presented an unreasonable danger to users of the product when put to its intended and reasonably anticipated use. Specifically, Defendants knew or should have known at the time they manufactured, labeled,

distributed, and sold the Cook Filter, which was implanted in Plaintiff, that the filter posed a significant risk of device failure.

169. Therefore, Defendants had a duty to warn of the risk of harm associated with the use of the device and to provide adequate instructions on the safe and proper use of the device. Defendants further had a duty to warn of dangers and proper safety instructions that it became aware of even after the device was distributed and implanted in Plaintiff.

170. Despite this duty, Defendants failed to adequately warn of material facts regarding the safety and efficacy of the Cook Filter, and further failed to adequately provide instructions on the safe and proper use of the device.

171. No health care provider, including Plaintiff's, or Plaintiff would have used the device in the manner directed, had those facts been made known to the prescribing healthcare providers and/or ultimate users of the device.

172. The health risks associated with the device as described herein are of such a nature that ordinary consumers would not have readily recognized the potential harm.

173. Plaintiff and Plaintiff's health care providers used the device in a normal, customary, intended, and foreseeable manner, namely as a surgically implanted device used to prevent pulmonary embolisms.

174. Therefore, the Cook Filter implanted in Plaintiff was defective and unreasonably dangerous at the time of release into the stream of commerce due to inadequate warnings, labeling and/or instructions accompanying the product.

175. The Cook Filter implanted in Plaintiff was in the same condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed, and sold by Defendants.

176. As a direct and proximate result of Defendants' lack of sufficient warning and/or instructions, Plaintiff has suffered and will continue to suffer serious physical injuries, pain and suffering, mental anguish, medical expenses, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

177. **WHEREFORE**, Plaintiff, LATISHA KENNINGTON, demands judgment against the Defendants COOK INCORPORATED, COOK MEDICAL LLC, and WILLIAM COOK EUROPE APS for whatever amount she may be entitled, together with costs of this action.

IX. COUNT V: NEGLIGENCE- DESIGN DEFECT

178. Plaintiff repeats and realleges all previous paragraphs and restates and incorporates the FACTUAL BACKGROUND section by reference.

179. At all times relevant to this action, Defendants developed, tested, designed, manufactured, inspected, labeled, promoted, distributed, and sold into the stream of commerce the Cook Filter, including the one implanted in Plaintiff.

180. The Cook Filter was expected to, and did, reach its intended consumers without substantial change in the condition in which it was in when it left Defendants' possession. In the alternative, any changes that were made to Cook Filter implanted in Plaintiff were reasonably foreseeable to Defendants.

181. The Cook Filter implanted in Plaintiff was defective in design because it failed to perform as safely as persons who ordinarily use the product would have expected at the time of use.

182. The Cook Filter implanted in Plaintiff was defective in design, in that its risks of harm exceeded its claimed benefits.

183. The Defendants knew that safer alternative designs were available and would have prevented or significantly reduced the risk of the injury presented by Cook Filter and it was economically and technologically feasible at the time the filter left the control of the Defendants to prevent or reduce the risk of such a such a dangerous event by application of existing, reasonably achievable, scientific knowledge.

184. Plaintiff and Plaintiff's health care providers used the Cook Filter in a manner that was reasonably foreseeable to Defendants.

185. Neither Plaintiff, nor Plaintiff's health care providers could have by the exercise of reasonable care discovered the devices defective condition or perceived its unreasonable dangers prior to Plaintiff's implantation with the device.

186. As a direct and proximate result of the Cook Filter's defective design, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

187. At all times relevant hereto, the Cook Filter was dangerous and presented a substantial danger to patients who were implanted with the Cook Filter and these risks and dangers were known or knowable at the times of distribution and implantation in Plaintiff in November 2011. Ordinary consumers would not have recognized the potential risks and dangers the Cook Filter posed to patients, because its use was specifically promoted to improve health of such patients. The Cook Filter was used by the Plaintiff and her treating physicians in a reasonably foreseeable manner.

188. The Defendants failed to provide warnings of such risks and dangers to the Plaintiff and her medical providers as described herein.

189. As a direct and proximate result of the Cook Filter's defects, as described herein, Plaintiff has suffered and will continue to suffer serious physical injuries, pain and suffering, mental anguish, medical expenses, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

190. **WHEREFORE**, Plaintiff LATISHA KENNINGTON demands judgment against the Defendants COOK INCORPORATED, COOK MEDICAL LLC, and WILLIAM COOK EUROPE APS for whatever amount she may be entitled, together with costs of this action.

X. COUNT VI: NEGLIGENCE- MANUFACTURER DEFECT

191. Plaintiff repeats and realleges all previous paragraphs and restates and incorporates the FACTUAL BACKGROUND section by reference.

192. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the Cook Filter that was implanted into Plaintiff.

193. The Cook Filter implanted in Plaintiff contained a condition, which Defendants did not intend; at the time it left Defendants' control and possession.

194. Plaintiff and Plaintiff's health care providers used the device in a manner that was reasonably foreseeable to Defendants.

195. As a result of this condition, the product injured Plaintiff and failed to perform as safely as the ordinary consumer would expect when used in a reasonably foreseeable manner.

196. As a direct and proximate result of the Cook Filter's manufacturing defect, Plaintiff has suffered and will continue to suffer serious physical injuries, pain and suffering, mental anguish, medical expenses, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

197. **WHEREFORE**, Plaintiff LATISHA KENNINGTON demands judgment against the Defendants COOK INCORPORATED, COOK MEDICAL LLC, and WILLIAM COOK EUROPE APS for whatever amount she may be entitled, together with costs of this action.

XI. COUNT VII: NEGLIGENCE MISREPRESENTATION

198. Plaintiff repeats and realleges all previous paragraphs and restates and incorporates the FACTUAL BACKGROUND section by reference

199. At all times relevant to this cause, and as detailed *supra*, Defendants negligently provided Plaintiff, Plaintiff's health care providers, and the general medical community with false or incorrect information, or omitted or failed to disclose material information concerning the Cook Filter, including, but not limited to, misrepresentations relating to the following subject areas:

a. The safety of the Cook Filter;

b. The efficacy of the Cook Filter;

c. The rate of failure of the Cook Filter; and

d. The approved uses of the Cook Filter.

200. The information distributed by Defendants to the public, the medical community and Plaintiff's health care providers was in the form of reports, press releases, advertising campaigns, labeling materials, print advertisements, commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the Cook Filter. Defendants made the foregoing misrepresentations knowing that they were false or without reasonable basis. These materials included instructions for use and warning document that was included in the package of the Cook Filter that was implanted in Plaintiff.

201. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiff's health care providers; to gain the confidence of the public and the medical community, including Plaintiff's health care providers; to falsely assure them of the quality of the Cook Filter and its fitness for use; and to induce the public and the medical community, including Plaintiff's healthcare providers to request, recommend, prescribe, implant, purchase, and continue to use the Cook Filter.

202. The foregoing representations and omissions by Defendants were in fact false. The Cook Filter is not safe, fit, and effective for human use in its intended and reasonably foreseeable manner. The use of the Cook Filter is hazardous to the user's health, and said device has a serious propensity to cause users to suffer serious injuries, including without limitation, the injuries Plaintiff suffered.

203. In reliance upon the false and negligent misrepresentations and omissions made by Defendants, Plaintiff and Plaintiff's health care providers were induced to, and did use the Cook Filter, thereby causing Plaintiff to sustain severe and permanent personal injuries.

204. Defendants knew and had reason to know that Plaintiff, Plaintiff's health care providers, and the general medical community did not have the ability to determine the true facts intentionally and/or negligently concealed and misrepresented by Defendants, and would not have prescribed and implanted same, if the true facts regarding the device had not been concealed and misrepresented by Defendants.

205. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects in the form of dangerous injuries and damages to persons who are implanted with the Cook Filter.

206. At the time Defendants failed to disclose and misrepresented the foregoing facts, and at the time Plaintiff used the Cook Filter, Plaintiff and Plaintiff's health care providers were unaware of said Defendants' negligent misrepresentations and omissions.

207. Plaintiff, Plaintiff's health care providers and general medical community reasonably relied upon misrepresentations and omissions made by Defendants where the concealed and misrepresented facts were critical to understanding the true dangers inherent in the use of the Cook Filter.

208. As a direct and proximate result of the Plaintiff and Plaintiff's health care provider's reliance on the foregoing misrepresentations and omissions by Defendants, as described herein, Plaintiff has suffered and will continue to suffer serious physical injuries, pain and suffering, mental anguish, medical expenses, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

209. **WHEREFORE**, the Plaintiff LATISHA KENNINGTON demands judgment against Defendants COOK INCORPORATED, COOK MEDICAL LLC, and WILLIAM COOK EUROPE APS, for whatever amount she may be entitled, together with costs of this action. as described herein.

XII. COUNT VIII: NEGLIGENCE PER SE

(Violation of 21 U.S.C. §§321, 331, 352 and 21 C.F.R. §§1.21 (Mar. 22, 1977), 801 (Feb. 13, 1976), 803 (Feb. 14, 2014), 806 (May 19, 1997), 807 (Aug. 23, 1977), 820 (Oct. 7, 1996))

210. Plaintiff repeats and realleges all previous paragraphs and restates and incorporates the FACTUAL BACKGROUND section by reference.

211. At all times herein mentioned, Defendants had an obligation not to violate the law, including the Federal Food, Drug and Cosmetic Act and the applicable regulations, in the

manufacture, design, testing, production, processing, assembling, inspection, research, promotion, advertising, distribution, marketing, promotion, labeling, packaging, preparation for use, consulting, sale, warning and post-sale warning and other communications of the risks and dangers of Cook IVC Filters.

212. By reason of its conduct as alleged herein, Cook failed to comply and/or violated provisions of mandatory statutes and regulations, including but not limited to, the following:

a. Cook violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 331 and 352, by misbranding its Cook IVC filters;

b. Cook violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §321 in making statements and/or representations via word, design, device or any combination thereof failing to reveal material facts with respect to the consequences that may result from the use of Cook IVC filters to which the labeling and advertising relates;

c. Cook violated 21 C.F.R. §1.21 in misleading the consumers and patients by concealing material facts in light of representations made regarding safety and efficacy of its Cook IVC Filters;

d. Cook violated 21 C.F.R. §801 in mislabeling its Cook IVC filters as to safety and effectiveness of its products and by failing to update its label to reflect post-marketing evidence that Cook IVC filters were associated with an increased risk of injuries due to tilting, fracture, migration and perforation;

e. Cook violated 21 C.F.R. §803 by not maintaining accurate medical device reports regarding adverse events of tilting, fracture, migration, perforation and complex

removal procedures and/or misreporting these adverse events maintained via the medical device reporting system;

f. Cook violated 21 C.F.R. § 806 by not maintaining accurate medical device reports regarding corrections or removals of the IVC filter to reduce or remedy health risks posed by the IVC filter via the medical device reporting system;

g. Cook violated 21 C.F.R. §807 by failing to notify the FDA and/or the consuming public when its Cook IVC filters were no longer substantially equivalent with regard to safety and efficacy with regard to post-marketing adverse events and safety signals; and

h. Cook violated 21 C.F.R. §820 by failing to maintain adequate quality systems regulation including, but not limited to, instituting effective corrective and preventative actions,

213. 21 U.S.C. §§321, 331, 352 and 21 C.F.R. §§1.21, 801, 803, 806, 807, 820 were and still are intended to protect a class of individuals, including Plaintiff individually, who lacked ability to protect themselves from medical devices like the Cook IVC filter.

214. The injuries and/or harm suffered by Plaintiff, where of the type and /or kind of occurrence that 21 U.S.C. §§321, 331, 352 and 21 C.F.R. §§1.21, 801, 803, 806, 807, 820 were intended and/or designed to prevent and/or guard against, regarding medical devices similar to the Cook IVC filter.

215. As a direct and proximate cause of the Cook Defendants' violations of 21 U.S.C. §§321, 331, 352 and 21 C.F.R. §§1.21, 801, 803, 806, 807, 820, as described herein, Plaintiff has suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future.

Plaintiff has lost the ability to live a normal life, and will continue to be so diminished into the future. Furthermore, Plaintiff has medical bills both past and future related to care because of the Cook Filter's violations.

216. The Cook Defendants' violations of 21 U.S.C. §§321, 331, 352 and 21 C.F.R. §§1.21, 801, 803, 806, 807, 820, as described herein, substantially contributed to Plaintiff's permanent and continuous injuries, pain and suffering, disability and impairment, emotional trauma, harm, and injuries that will continue into the future.

217. **WHEREFORE**, Plaintiff demands judgment against the Cook Defendants and seeks damages, including compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and other such other and further relief as the Court deems just and proper.

XIII. COUNT IX: BREACH OF EXPRESS WARRANTY

218. Plaintiff repeats and realleges all previous paragraphs. Plaintiff repeats and realleges all previous paragraphs and restates and incorporates the FACTUAL BACKGROUND section by reference.

219. Plaintiff, through her medical providers, purchased her Cook IVC filter from the Cook Defendants.

220. At all times relevant to their cause of action, the Cook Defendants were merchants and/or sellers of goods of the kind including medical devices and vena cava filters (i.e., Cook IVC filters).

221. At the time and place of sale, distribution, bargain, and supply of the Cook IVC filter to Plaintiff (and to other consumers and the medical community), Cook expressly represented, affirmed, warranted, described, and promised in their marketing materials, both

written and orally, and in the IFUs, that the Cook IVC filters were safe, well-tolerated, efficacious, and fit for their intended purpose and were of marketable quality, that they did not produce any unwarned-of dangerous side effects, and that they were adequately tested.

222. Plaintiff read, heard, saw, or knew of Defendant Cook's promises, warranties, affirmations, and/or representations in their marketing materials, both written and orally, and in the IFUs, that the Cook IVC filters were safe, well-tolerated, efficacious, and fit for their intended purpose and were of marketable quality, that they did not produce any unwarned-of dangerous side effects, and that they were adequately tested.

223. Plaintiff relied on Defendant Cook's promises, warranties, affirmations, and/or representations and that the filters were safe, well-tolerated, efficacious, and fit for their intended purpose and were of marketable quality, that they did not produce any unwarned-of dangerous side effects, and that they were adequately tested when determining whether or not to have the Cook IVC filter implanted.

224. Ordinary consumers, including Plaintiff, would have reasonably relied on Defendant Cook's express factual representations, warranties, and promises in their marketing materials, both written and orally, and in the IFUs, that the Cook IVC filters were safe, well-tolerated, efficacious, and fit for their intended purpose and were of marketable quality, that they did not produce any unwarned-of dangerous side effects, and that they were adequately tested when determining to purchase and/or use the Cook IVC filter.

225. At the time of Plaintiff's purchase from the Cook Defendants, the Cook IVC filter was not in a merchantable condition and the Cook Defendants breached their expressed warranties, in that the filter:

a. was designed in such a manner so as to be prone to an unreasonably high incident of fracture, perforation of vessels and organs, and/or migration;

b. was designed in such a manner so as to result in an unreasonably high incident of injury to the organs of its purchaser; and

c. was manufactured in such a manner so that the exterior surface of the Cook IVC filter was inadequately, improperly and inappropriately designed causing the device to weaken and fail.

226. At the time of Plaintiff's purchase from the Cook Defendants, the Cook IVC filter did not comply, conform, and/or perform per with Cook's affirmations and promises, in that the filter:

a. was designed in such a manner so as to be prone to an unreasonably high incident of fracture, perforation of vessels and organs, and/or migration;

b. was designed in such a manner so as to result in an unreasonably high incident of injury to the organs of its purchaser; and

c. was manufactured in such a manner so that the exterior surface of the Cook IVC filter was inadequately, improperly and inappropriately designed causing the device to weaken and fail.

227. Plaintiff took reasonable steps to notify the Cook Defendants within a reasonable time that the Cook IVC filter as warranted, described, and promised in their marketing materials, both written and orally, and in the IFUs, was not safe, nor well-tolerated, nor efficacious, and fit for their intended purpose and were of marketable quality, that they did produce unwarned-of dangerous side effects, and that they were not adequately tested.

228. As a direct and proximate result of the Cook IVC filter's defects and Cook's noncompliance of the affirmations and promises, as described herein, Plaintiff has suffered permanent and continuous injuries, pain and suffering, disability, and impairment. Plaintiff suffered emotional trauma, harm, and injuries that will continue into the future. Plaintiff has lost their ability to live a normal life and will continue to be so diminished into the future. Furthermore, Plaintiff has lost earnings and will continue to lose earnings into the future and have medical bills both past and future related to care because of the Cook IVC filter's defect.

229. The Cook Defendants' noncompliance of the affirmations and promises, as described herein, substantially contributed to Plaintiff's permanent and continuous injuries, pain and suffering, disability and impairment, emotional trauma, harm, and injuries that will continue into the future.

230. By reason of the foregoing, the Cook Defendants are liable to Plaintiff for damages as a result of their breach express warranty.

231. **WHEREFORE**, Plaintiff demands judgment against the Cook Defendants and seeks damages, including compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and other such other and further relief as the Court deems just and proper.

XIV. COUNT X: BREACH OF IMPLIED WARRANTY

232. Plaintiff repeats and realleges all previous paragraphs. Plaintiff repeats and realleges all previous paragraphs and restates and incorporates the FACTUAL BACKGROUND section by reference.

233. Plaintiff, through their medical providers, purchased their Cook IVC filter from the Cook Defendants.

234. At all relevant and material times, the Cook Defendants manufactured, distributed, advertised, promoted, and sold their Cook IVC filters.

235. At all relevant times, the Cook Defendants intended their Cook IVC filters be used in the manner that Plaintiff in fact used them and/or could reasonably foresee the Plaintiff's manner of use for the Cook IVC filter.

236. At all relevant times, the Cook Defendants had reason to know that their Cook IVC filters would be used in the manner that Plaintiff in fact used them and/or could reasonably foresee the Plaintiff's manner of use for the Cook IVC filter.

237. The Cook Defendants impliedly warranted their Cook IVC filters to be of merchantable quality, safe and fit for the ordinary and/or particular use for which the Cook Defendants intended them and for which Plaintiff in fact used them.

238. The Cook Defendants breached their implied warranties as follows:

a. Cook failed to provide the warning or instruction and/or an adequate warning or instruction which a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that its Cook IVC filters would cause harm;

b. Cook manufactured and/or sold its Cook IVC filters in a manner that would cause objection by other IVC filter manufacturers based on the descriptions contained in Cook's marketing materials, both written and orally, and in the IFU;

c. Cook manufactured and/or sold its Cook IVC filters in a manner that would cause objection by ordinary consumers, including Plaintiff, based on the descriptions contained in Cook's marketing materials, both written and orally, and in the IFU;

d. Cook manufactured and/or sold its Cook IVC filters with a below average quality that failed to meet the descriptions contained in Cook's marketing materials, both written and orally, and in the IFU;

e. Cook manufactured and/or sold their Cook IVC filters and said filters did not conform to representations made by the Cook Defendants when they left their control;

f. The Cook IVC filter was not fit for the ordinary purpose described in Cook's marketing materials, both written and orally, and in the IFU in that the Cook IVC filter was prone to an unreasonably high incident of fracture, perforation of vessels and organs, and/or migration;

g. Cook manufactured and/or sold its Cook IVC filters which were more dangerous than an ordinary consumer would expect when used in an intended or reasonably foreseeable manner, and the foreseeable risks associated with the Cook IVC filters' design or formulation exceeded the benefits associated with that design. These defects existed at the time the products left the Cook Defendants' control;

h. The Cook IVC filter did not conform to the representations, affirmations, warranties, and promises found within the Cook IVC filter's containers, packages, labels, marketing materials, both written and orally, and in the IFU;

i. Cook manufactured and/or sold its Cook IVC filters when they deviated in a material way from the design specifications, formulas, quality, or performance standards or from otherwise identical units manufactured to the same design specifications, formulas, quality, or performance standards, and these defects existed at the time the products left the Cook Defendants' control; and

j. Cook manufactured and/or sold its Cook IVC filters with inadequate containers, packages, and labels which a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that its Cook IVC filters would cause harm.

239. At the time of Plaintiff's purchase from the Cook Defendants, the Cook IVC filter did not comply, conform, and/or perform per with Cook's affirmations and promises, contained on or within the containers and/or labels, in that the filter:

a. was designed in such a manner so as to be prone to a unreasonably high incident of fracture, perforation of vessels and organs, and/or migration;

b. was designed in such a manner so as to result in an unreasonably high incident of injury to the organs of its purchaser; and

c. was manufactured in such a manner so that the exterior surface of the Cook IVC filter was inadequately, improperly and inappropriately designed causing the device to weaken and fail.

240. The Cook Defendants' marketing of their Cook IVC filters was false and/or misleading.

241. Plaintiff, through their attending physicians, relied on these representations in determining which IVC filter to use for implantation in the Plaintiff.

242. Cooks' IVC filters were unfit and unsafe for use by users as they posed an unreasonable and extreme risk of injury to persons using said products, such as the Plaintiff, and accordingly the Cook Defendants breached their expressed warranties and the implied warranties associated with the product.

243. Cook IVC filters were defective and unreasonably dangerous when they left the possession of the Defendants and at the time they reached Plaintiff, in that they contained warnings/instructions insufficient and/or inadequate to alert consumers, including Plaintiff who read, heard, saw, believed, and/or knew of Defendant Cook's promises, affirmations, and/or representations in their marketing materials, both written and orally, and in the IFUs, that the Cook IVC filters were safe, well-tolerated, efficacious, and fit for their intended purpose and were of marketable quality, that they did not produce any unwarned-of dangerous side effects, and that they were adequately tested; yet was not made aware of the dangerous risks associated with the subject product, including but not limited to the risk of tilting, perforation, fracture and migration which are associated with and did cause serious injury and/or death.

244. Plaintiff took reasonable steps to notify the Cook Defendants within a reasonable time that the Cook IVC filter quality as warranted, described, and promised in their marketing materials, both written and orally, and in the IFUs, was not safe, nor well-tolerated, nor efficacious, and fit for their intended purpose and were of marketable quality, that they did produce unwarned-of dangerous side effects, and that they were not adequately tested.

245. The Cook Defendants' IVC filter's lack of quality, as described herein, substantially contributed to Plaintiff's permanent and continuous injuries, pain and suffering, disability and impairment, emotional trauma, harm, and injuries that will continue into the future.

246. The foregoing warranty breaches were a substantial factor in causing Plaintiff's injuries and damages as alleged.

247. As a direct and proximate result of the Cook IVC filters' defects, as described herein, Plaintiff has suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue

into the future. Plaintiff has lost her ability to live a normal life and will continue to be so diminished into the future. Furthermore, Plaintiff has lost earnings and will continue to lose earnings into the future and has medical bills both past and future related to care because of the Cook IVC filters' defects.

248. By reason of the foregoing, Defendants are liable to the Plaintiff for damages as a result of its breaches of implied warranty.

249. **WHEREFORE**, Plaintiff demands judgment against the Cook Defendants and seeks damages, including compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and other such other and further relief as the Court deems just and proper.

XV. COUNT XI: VIOLATIONS OF IDAHO LAW PROHIBITING CONSUMER FRAUD AND UNFAIR DECEPTIVE TRADE PRACTICES

250. Plaintiff repeats and realleges all previous paragraphs and restates and incorporates the FACTUAL BACKGROUND section by reference.

251. This Suit is filed pursuant to the provisions Id. Code § 48.601, et seq. of the IDAHO Consumer Protection Act ("ICPA") upon grounds that the acts and procedures of Cook as described in this Complaint are prohibited by the Statute, including but not limited to §48.

252. The Cook Defendants had a statutory duty to refrain from unfair or deceptive acts or practices in the sale and promotion of Cook IVC filters to Plaintiff.

253. The Cook Defendants engaged in unfair, unconscionable, deceptive, fraudulent and misleading acts or practices in violation of IDAHO 's consumer protection laws Id. Code § 48.601, et seq.

254. Through its false, untrue and misleading promotion of Cook IVC filters, as described herein, which were read, heard, seen, known of, and relied on by Plaintiff, the Cook

Defendants induced Plaintiff, as described herein, to purchase and/or pay for the purchase of the Cook IVC filter at issue.

255. The Cook Defendants misrepresented the alleged benefits, quality, grade, standard, or characteristics of Cook's IVC filters; suppressed, omitted, concealed, and failed to disclose material information concerning known adverse effects of Cook IVC filters, as described herein; misrepresented the quality and efficacy of Cook IVC filters as compared to much lower-cost alternatives, as described herein; misrepresented and advertised that Cook IVC filters were of a particular standard, quality, or grade that they were not, as described herein; misrepresented Cook IVC filters in such a manner that later, on disclosure of the true facts, there was a likelihood that Plaintiff would have opted for an alternative IVC filter or method of preventing pulmonary emboli.

256. The Cook Defendants' conduct created a likelihood of, and in fact caused, confusion and misunderstanding, as described herein. The Cook Defendants' conduct misled, deceived, and damaged Plaintiff, as described herein; and the Cook Defendants' fraudulent, misleading, and deceptive conduct was perpetrated with an intent that Plaintiff rely on said conduct by purchasing and/or paying for a purchase of a Cook IVC filter. Moreover, the Cook Defendants knowingly took advantage of Plaintiff, as described herein, who was reasonably unable to protect her interests due to ignorance of the harmful adverse effects of Cook's IVC filters.

257. The Cook Defendants' conduct was willful, outrageous, immoral, unethical, oppressive, unscrupulous, unconscionable, and substantially injurious to Plaintiff and offends the public conscience.

258. Plaintiff was induced by Cook as described herein and as a result purchased her Cook IVC filter primarily for personal, family, or household purposes.

259. As a result of the Cook Defendants' violative conduct in IDAHO and throughout the United States, Plaintiff purchased and/or paid for a purchase of a Cook IVC filter that was not made for resale.

260. **WHEREFORE**, Plaintiff demands judgment against the Cook Defendants and seeks damages, including compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and other such other and further relief as this Court deems just and proper.

XVI. COUNT XII: FRAUDULENT CONCEALMENT

261. Plaintiff repeats and realleges all previous paragraphs. Plaintiff further restates and incorporates the FACTUAL BACKGROUND section by reference and alleges further:

262. At the time and place of sale, distribution, bargain, and supply of the Cook IVC filter to Plaintiff (and to other consumers and the medical community), Cook expressly represented, warranted, described, and promised in their marketing materials, both written and orally, and in the IFUs, that the Cook IVC filters were safe, well-tolerated, efficacious, and fit for their intended purpose and were of marketable quality, that they did not produce any unwarned-of dangerous side effects, and that they were adequately tested.

263. At the time and place of sale, distribution, bargain, and supply of the Cook IVC filter to Plaintiff (and to other consumers and the medical community), Cook knew that their express representations, warranties, descriptions, and promises in their marketing materials, both written and orally, and in the IFUs, that the Cook IVC filters were safe, well-tolerated, efficacious, and fit for their intended purpose and were of marketable quality, that they did not

produce any unwarned-of dangerous side effects, and that they were adequately tested were false.

264. Cook IVC filters were defective and unreasonably dangerous when they left the possession of the Defendants in that they contained warnings/instructions insufficient and/or inadequate to alert consumers, including Plaintiff, of the dangerous risks associated with the subject product, including but not limited to the risk of tilting, perforation, fracture and migration which are associated with and did cause serious injury and/or death.

265. The Cook Defendants knew or recklessly and/or willfully disregarded the fact that the Cook IVC filters were defective and unreasonably dangerous when they left the possession of the Defendants in that they contained warnings/instructions insufficient and/or inadequate to alert consumers, including Plaintiff, of the dangerous risks associated with the subject product, including but not limited to the risk of tilting, perforation, fracture and migration which are associated with and did cause serious injury and/or death.

266. Cook IVC filters were defective and unreasonably dangerous before they left the possession of the Defendants and at the time they reached Plaintiff in November 2011, in that they contained warnings/instructions insufficient and/or inadequate to alert consumers, including Plaintiff who read, heard, saw, believed, and/or knew of Defendant Cook's promises, affirmations, and/or representations in their marketing materials, both written and orally, and in the IFUs, that the Cook IVC filters were safe, well-tolerated, efficacious, and fit for their intended purpose and were of marketable quality, that they did not produce any unwarned-of dangerous side effects, and that they were adequately tested; yet was not made aware of the dangerous risks associated with the subject product, including but not limited to the risk of

tilting, perforation, fracture and migration which are associated with and did cause serious injury and/or death.

267. The Cook Defendants either actually knew of, should have, or could reasonably foresee that Plaintiff was a direct or reasonably foreseeable user, or person in Plaintiff's position might reasonably be expected to come in contact with the Cook IVC filter.

268. Cook made affirmative, independent efforts to conceal the dangerous risks associated with the subject product, including but not limited to the risk of tilting, perforation, fracture and migration which are associated with and did cause serious injury and/or death, yet marketed the Cook IVC filters without adequately warning of the danger or providing instructions for safe use; in order to mislead and/or deceive ordinary consumers, including Plaintiff, into relying on the fraudulent promises, affirmations, and/or representations in their marketing materials, both written and orally, and in the IFUs.

269. The Cook Defendants disclosed the alleged health benefits of the Cook IVC filter, but made affirmative, independent efforts to conceal the dangerous risks associated with the subject product, including but not limited to the risk of tilting, perforation, fracture and migration which are associated with and did cause serious injury and/or death, yet marketed the Cook IVC filters without adequately warning of the danger or providing instructions for safe use.

270. The Cook Defendants had sole and/or private knowledge regarding the dangerous risks of the Cook IVC filter, yet made affirmative, independent efforts to conceal the dangerous risks associated with the subject product, including but not limited to the risk of tilting, perforation, fracture and migration which are associated with and did cause serious injury and/or death, yet marketed the Cook IVC filters without adequately warning of the danger or providing instructions for safe use.

271. Plaintiff was not aware of and/or could not have discovered the concealed dangerous risks associated with the subject product, including but not limited to the risk of tilting, perforation, fracture and migration which are associated with and did cause serious injury and/or death.

272. The Cook Defendants independent efforts to conceal the dangerous risks associated with the subject product, including but not limited to the risk of tilting, perforation, fracture and migration which are associated with and did cause serious injury and/or death, was intended to and did deceive Plaintiff regarding the dangerous risks of the Cook IVC filter.

273. The Cook Defendants had a duty to disclose the dangerous risks associated with the subject product, including but not limited to the risk of tilting, perforation, fracture and migration which are associated with and did cause serious injury and/or death.

274. Plaintiff detrimentally and justifiably relied and/or acted on The Cook Defendants' misinformation regarding information, labels, and warnings that were insufficient and/or inadequate to alert consumers, including Plaintiff, of the dangerous risks associated with the subject product, including but not limited to the risk of tilting, perforation, fracture and migration which are associated with and did cause serious injury and/or death.

275. The Cook IVC filter's absence of a sufficient warnings or instructions rendered the filter unreasonably dangerous to Plaintiff.

276. Information provided by Cook to the medical community and to consumers concerning the safety and efficacy of its Cook IVC filters did not accurately reflect the serious and potentially fatal adverse events Plaintiff could suffer.

277. At all times relevant hereto, the Cook IVC filters were dangerous and presented a substantial danger to patients who were implanted with the Cook IVC filter, and these risks and

dangers were known or knowable at the times of distribution and implantation in Plaintiff. Ordinary consumers would not have recognized the potential risks and dangers the Cook IVC filters posed to patients, because their use was specifically promoted to improve health of such patients.

278. Had adequate warnings, instructions, and information been provided and/or disclosed, Plaintiff reasonably would have behaved differently, would not have been implanted with the Cook IVC filter, and would not have been at risk of the harmful injuries described herein. The Cook Defendants failed to provide warnings of such risks and dangers to Plaintiff and her medical providers as described herein. Neither Plaintiff, nor Plaintiff's physicians knew, nor could they have learned through the exercise of reasonable care, the risks of serious injury and/or death associated with and/or caused by Cook's IVC filters.

279. Had adequate warnings and instructions been provided, Plaintiff and/or Plaintiff's physician would have followed the Cook IVC filter's warnings or instructions and Plaintiff would not have been at risk of the harmful injuries described herein. The Cook Defendants failed to provide warnings of such risks and dangers to Plaintiff and her medical providers as described herein. Neither Plaintiff, nor Plaintiff's physicians knew, nor could they have learned through the exercise of reasonable care, the risks of serious injury and/or death associated with and/or caused by Cook's IVC filters.

280. A reasonably prudent manufacturer in the same or similar circumstances would have provided with respect to the risks of serious injury and/or death associated with and/or caused by Cook's IVC filters and would have communicated adequate information on the risks of serious injury and/or death associated with and/or caused by Cook's IVC filters and safe use

of the Cook IVC filter, taking into account the characteristics of, and the ordinary knowledge common to, the persons by whom the product is intended to be used.

281. Cook Defendants Cook made affirmative, independent efforts to conceal the increased risks of serious injury and/or death associated with and/or caused by Cook IVC filters.

282. Plaintiff, individually and through her implanting physician, reasonably relied upon the skill, superior knowledge and judgment of the Cook Defendants.

283. Cook Defendants were under a continuing duty to warn Plaintiff and her physicians of the dangers associated with the filter.

284. Safer alternatives were available that were effective and without risks posed by Cook's IVC filters.

285. As a direct and proximate result of the Cook IVC filter's defects and the Cook Defendants' concealment of the dangerous risks associated with the subject product, as described herein, Plaintiff suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost her ability to live a normal life and will continue to be so diminished into the future. Furthermore, Plaintiff has medical bills, both past and future, related to care because of the Cook IVC filters' defects.

286. The Cook Defendants' concealment of the dangerous risks associated with the subject product, as described herein, substantially contributed to Plaintiff's permanent and continuous injuries, pain and suffering, disability and impairment, emotional trauma, harm, and injuries that will continue into the future. The Defendants are and were under a continuing duty to disclose the true character, quality and nature of the device that was implanted in Plaintiff, but instead they concealed them. Defendants' conduct, as described in this complaint, amounts to

conduct purposely committed, which Defendants must have realized was dangerous, heedless, and reckless, without regard to the consequences or the rights and safety of Plaintiff.

287. Defendants expressly and impliedly warranted that the Cook IVC Filter was a permanent lifetime implant and downplayed the risks associated with migration, perforation, tilt, fracture and other risks relied upon by the Plaintiff to her detriment.

288. Cook suppressed, omitted, concealed, and failed to disclose material information about the known adverse events and lack of efficacy in the Tulip "Patient Guide."

289. The patient guide conceals the known nature, frequency, and extent of serious failure modes and associated adverse events associated with the Tulip filter.

290. The patient guide conceals the severity and frequency of embedded filters and the associated progressive injury Cook knew to be associated with the Tulip filter.

291. The patient guide conceals the know frequency of penetration and perforation into other organs associated with the Tulip filter.

292. The patient guide conceals that the reported deaths associated with use of the Tulip filter exceed that reported with some competitor products.

293. This concealment deprived Plaintiff and her physician of the data needed to perform an informed risk/benefit analysis. This concealment deprived Plaintiff of the information she needed to discover a potential cause of action against Cook.

294. The "Instructions for Use" omits important information known to Cook regarding retrievability and adverse events.

295. The IFU is silent as to the adverse events that occurred in the Tulip clinical pilot study and claims that there were "none."

296. Cook routinely and systematically were silent in their advertising to physicians

that the Tulip was not safe for retrieval after 14 days and instead claimed that the Cook Filters could be retrieved at any time.

297. Cook defined the retrieval period for the Tulip filters as indefinite.

298. Cook fraudulently concealed information with respect to the Tulip filter in the following particulars:

a. Cook represented through their IFUs, advertising, marketing materials, and regulatory submissions that the Tulip filter was safe and fraudulently withheld and concealed information about the severity of the substantial risks of using the Tulip Filter; and

b. Upon information and belief, Cook represented that the Tulip Filter was safer than other alternative filters and fraudulently concealed information which demonstrated that the Tulip filter was not safer than alternatives available on the market.

299. Cook was under a duty to Plaintiff to disclose and warn of the defective and dangerous nature of the Tulip filter because:

c. Cook had sole access to material facts concerning, and unique and special expertise regarding, the dangers and unreasonable risks of the Tulip filter;

d. Cook knowingly made false claims and omitted important information about the safety and quality of the Tulip filter in the documents and marketing materials Cook provided to physicians and the general public; and

e. Cook fraudulently and affirmatively concealed the defective and dangerous nature of the Tulip filter from Plaintiff.

300. As the designers, manufacturers, sellers, promoters, and/or distributors of the

Tulip filter, Cook had unique knowledge and special expertise regarding the Tulip filter. This placed them in a position of superiority and influence over Plaintiff and her healthcare providers. As such, Plaintiff and her healthcare providers reasonably placed her trust and confidence in Cook and in the information disseminated by Cook.

301. The facts concealed or not disclosed by Cook to Plaintiff were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase the Cook Filter.

302. The concealment of information and the misrepresentations about the Gunther filter were made by Cook with the intent that doctors and patients, including Plaintiff, rely upon them so that Plaintiff would request the Tulip filter and her health care providers would recommend the Gunther filter.

303. Plaintiff, her doctors, and others reasonably relied on Cook's representations and were unaware of the substantial risk posed by the Tulip filter.

304. Had Cook not concealed or suppressed information regarding the severity of the risks of the Tulip filter, Plaintiff and her physicians would not have used the Tulip filter.

305. Cook, by concealment or other action, intentionally prevented Plaintiff and her health care professionals from acquiring material information regarding the lack of safety of the Tulip filter, thereby preventing Plaintiff from discovering the truth.

306. By reason of the foregoing, Cook Defendants are liable to Plaintiff for damages as a result of their fraudulent concealment from the Plaintiff and her healthcare professionals about the increased risk of serious injury and death caused by their defective Cook IVC filters.

307. **WHEREFORE**, Plaintiff demands judgment against the Cook Defendants and seeks damages, including compensatory damages, exemplary damages, and punitive damages,

together with interest, the costs of suit and attorneys' fees, and other such other and further relief as the Court deems just and proper.

XVII. COUNT XIII: CORPORATE/VICARIOUS LIABILITY

308. Plaintiff repeats and realleges all previous paragraphs and restates and incorporates the FACTUAL BACKGROUND section by reference.

309. At all times herein mentioned, the Cook Defendants were agents, servants, partners, aiders and abettors, co-conspirators, and/or joint venturers, and were at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy, and/or joint venture and rendered substantial assistance and encouragement to each other, knowing that their collective conduct constituted a breach of duty owed to the Plaintiff.

310. There exists and, at all times herein mentioned, there existed a unity of interest in ownership between the Cook Defendants such that any individuality and separateness between them have ceased and these Cook Defendants are alter egos. Adherence to the fiction of the separate existence of these Cook Defendants as entities distinct from each other will permit an abuse of the corporate privilege and would sanction a fraud and/or would promote injustice.

311. At all times herein mentioned, the Cook Defendants, and each of them, were engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing, advertising for sale, and/or selling products for use by the Plaintiff. As such, each Defendant is individually, as well as jointly and severally, liable to the Plaintiff for Plaintiff's damages.

312. At all times herein mentioned, the officers and/or directors of the Cook Defendants participated in, authorized and/or directed the production, marketing, promotion, and sale of the aforementioned products when they knew, or with the exercise of reasonable care and diligence should have known, of the hazards and dangerous propensities of said products, and thereby actively participated in the tortious conduct that resulted in the injuries suffered by the Plaintiff.

313. As a foreseeable, direct, and proximate consequence of Cook's actions, omissions, and misrepresentations, Plaintiff suffered an injury related to the Tulip filter. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

XVIII. COUNT XIV: PUNITIVE DAMAGES

314. Plaintiff repeats and realleges all previous paragraphs and restates and incorporates the FACTUAL BACKGROUND section by reference.

315. At all times material hereto, the Cook Defendants knew or should have known their Cook IVC filters had and/or have a high probability of being inherently dangerous with respect to the risk of tilt, fracture, migration and/or perforation and despite that knowledge intentionally failed to disclose that the Cook IVC filters were dangerous and presented a

substantial danger to patients who were implanted with the Cook IVC filter, and these risks and dangers were known or knowable at the times of distribution and implantation in Plaintiff.

316. At all times material hereto, the Cook Defendants attempted to misrepresent and did knowingly misrepresent facts concerning the safety of their Cook IVC filters.

317. The Cook Defendants' misrepresentations included knowingly withholding and/or concealing material information and facts from the medical community and the public, including Plaintiff and Plaintiff's physicians, concerning the safety of their Cook IVC filters to deprive the medical community and the public, including Plaintiff and Plaintiff's physicians of crucial information and cause harm. The Cook Defendants' conduct was knowing, willful, wanton, careless, fraudulent, reckless, malicious, conscious, despicable, intentional, oppressive, deliberate, and undertaken with a conscious indifference to the cruel and unjust consequences and/or hardship that consumers of their product faced, including Plaintiff.

318. At all times material hereto, Cook knew and recklessly disregarded the fact that their Cook IVC filters have an unreasonably high rate of tilt, fracture, migration and/or perforation.

319. Notwithstanding the foregoing, the Cook Defendants continued to market their Cook IVC filters aggressively to consumers, including the Plaintiff, without disclosing the aforesaid side effects.

320. The Cook Defendants knew of their Cook IVC filters' lack of warnings regarding the risk of fracture, migration, and/or perforation, but intentionally concealed and/or recklessly failed to disclose that risk and continued to market, distribute, and sell their Cook IVC filters without said warnings so as to maximize sales and profits at the expense of the health and safety

of the public, including Plaintiff, in a willful and conscious disregard of the foreseeable harm caused by Cook IVC filters to others, including Plaintiff.

321. The Cook Defendants' intentional and/or reckless failure to disclose information deprived the Plaintiff's physicians of necessary information to enable them to weigh the true risks of using Cook IVC filters against their benefits.

322. As a direct and proximate result of the Cook Defendants' knowing, willful, wanton, careless, fraudulent, reckless, malicious, conscious, despicable, intentional, oppressive, and deliberate disregard for the safety and rights of consumers including the Plaintiff, the Plaintiff has suffered and will continue to suffer severe and permanent physical and emotional injuries, as described with particularity, above. Plaintiff has endured and will continue to endure pain, suffering, and loss of enjoyment of life; and has suffered and will continue to suffer economic loss, including incurring significant expenses for medical care and treatment and lost wages.

323. The Cook Defendants' aforesaid conduct was committed with knowing, willful, wanton, careless, fraudulent, reckless, malicious, conscious, despicable, intentional, oppressive, and deliberate disregard for the safety and rights of consumers including the Plaintiff, thereby entitling the Plaintiff to punitive damages in an amount appropriate to punish the Cook Defendants and deter them from similar conduct in the future.

324. **WHEREFORE**, Plaintiff demands judgment against the Cook Defendants and seeks damages, including compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and other such other and further relief as the Court deems just and proper.

XIX. COUNT XV: THE CASE FOR MEDICAL MONITORING

325. Plaintiff repeats and re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs above as though fully set forth herein.

326. In certain cases, medical monitoring is required to evaluate whether a Cook Filter (or portions of the Cook Filter) has fractured, tilted and/or migrated (collectively referred to herein as "device failure" or "failure"). In order to determine whether failure of the Cook Filter has occurred, imaging studies must be performed. Typically, these imaging studies will include un-enhanced computed tomography scan (CT Scan) so that the filter may be visualized. CT Scan imaging produces an image of the filter and is able to reveal whether the filter has fractured or migrated.

327. Patients requiring medical monitoring are recommended to undergo regular and frequent imaging studies of the device or portions of the device at least once or twice annually. As long as the device, or portions of the device, remains within the body of the patient, the potential for future device failure exists. Consequently, these patients require regular and frequent medical monitoring for the duration of time the device, or portions of the device, remain within their bodies.

328. Patients eligible for medical monitoring for the Cook Filter or portions of the device need not have experienced past failure of the Cook Filter. For example, patients who have undergone implant of the Cook Filter frequently learn that the Cook Filter cannot be removed due to the fact that it has "grown into" tissue, but the fracture, tilt or migration of the device may not yet have occurred. As a result of the inability to remove the Cook Filter, the device must remain permanently implanted in the patient, for the patient's lifetime. Although these patients may not yet have experienced device failure, they are at risk for

future device failure and require regular and frequent monitoring to evaluate the integrity of the Cook Filter. In addition to the aforementioned imaging studies, endovascular intervention (typically cardiac catheterization) may also be used by medical professionals to diagnose or discover whether fractured portions of the Cook Filter System have migrated to the heart or lungs. Furthermore, endovascular surgery may assess the nature and extent of the damage resulting from failure of the Cook Filter.

329. In those instances where device fracture has occurred, and depending on the circumstances particular to the patient, a person may be required to undergo one or all of the following medical procedures:

a. CT Scanning or other imaging studies;

b. Cardiac Catheterization;

c. Open heart surgery;

d. Removal of the Cook Filter from the vena cava.

330. The Cook Filter was placed in Plaintiff's body on or about November 2011. The Cook Filter subsequently has perforated her IVC and her iliac vein, causing abdominal pain. Plaintiff has incurred significant medical expenses and has endured physical pain and suffering, mental anguish, loss of enjoyment of life, and other losses, some of which are permanent in nature. Plaintiff is required to attend regular physicians' visits and to undergo imaging studies.

331. As a direct and proximate result of the conduct and defective product of the Defendants, as alleged in this Complaint, medical monitoring is necessary for Plaintiff. Medical monitoring includes.

a. Regularly scheduled CT scans or other appropriate imaging studies; and/or

b. Potential cardiac catheterization or other endovascular procedure to detect the presence of migrated pieces of the Cook Filter System; and/or Physicians' visits and examinations.

XX. TOLLING OF THE LIMITATIONS PERIOD

332. The Cook Defendants, through affirmative misrepresentations and omissions, actively concealed from the Plaintiff and Plaintiff's healthcare providers the true and significant risks associated with Cook IVC filters to deceive Plaintiff into having a Cook IVC filter implanted.

333. As a result of the Cook Defendants' actions, Plaintiff and their prescribing physicians were unaware, and could not have reasonably known, learned, or discovered through reasonable diligence, that Plaintiff had been exposed to the risks identified in their Complaint, and that those risks were the result of Defendants' acts, omissions, and misrepresentations.

334. As a result of the Cook Defendants' affirmative misrepresentations, active concealment, and omissions, Plaintiff was debarred and deterred, despite reasonable diligence, from being able to bring forth a cause of action and bring forth the allegations and risks identified in this Complaint.

335. Accordingly, no limitations period ought to accrue until such time as Plaintiff knew or reasonably should have known, been made aware, and/or discovered some causal connection between Plaintiff being implanted with a Cook IVC filter and the harm Plaintiff suffered as a result.

336. Additionally, the accrual and running of any applicable statute of limitations have been tolled by reason of the Cook Defendants' fraudulent concealment.

337. Additionally, the Cook Defendants are equitably estopped from asserting any limitations defense by virtue of their fraudulent concealment and other misconduct as described.

338. Additionally, the limitations period ought to be tolled under principles of equitable tolling.

XXI. PRAYER FOR RELIEF

339. **WHEREFORE**, Plaintiff demands judgment against the Cook Defendants as follows:

a. Compensatory damages, including without limitation past and future medical expenses; past and future pain and suffering; past and future emotional distress; past and future loss of enjoyment of life; past and future lost wages and loss of earning capacity; and consequential damages, due to the filter fracturing, perforating her vertebrae, and causing her severe pain and stenosis;

b. Punitive damages in an amount sufficient to punish Defendants and set an example;

c. Disgorgement of profits;

d. Restitution;

e. Costs and fees of their action, including reasonable attorney's fees;

f. Prejudgment interest and all other interest recoverable; and

g. Such other additional and future relief as Plaintiff may be entitled to in law or in equity according to the claims pled herein.

DEMAND FOR JURY TRIAL

Plaintiff respectfully requests trial by jury in the above case as to all issues.

Date: March 7, 2023.

By: /s/Wes S. Larsen

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